



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: August 27, 2018

SUBJECT: Efficacy VigorOx® Liquid Sanitizer and Disinfectant
EPA Reg. No. 65402-1
DP Barcode: 447271

FROM: Lorilyn Montford
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TO: Zeno Bain, PM 33/Terria Northern
Regulatory Management Branch I
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APPLICANT: PeroxyChem, LLC
2005 Market St. Ste. 3200
Philadelphia PA 19103-7014

FORMULATION FROM LABEL:

<u>Active Ingredient</u>	<u>% by wt.</u>
Peroxyacetic Acid.....	5.1%
Hydrogen Peroxide.....	21.7%
Other Ingredients.....	73.2%
Total.....	100.0%

I. BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s): sanitizer and disinfectant (bactericide and virucide) for use in industrial, institutional and commercial facilities such as medical, veterinary, dairies, wineries, schools, and food processing environments.

Requested action(s): Add disinfection claims against an additional virus

Documents considered in this review:

- EPA Form 8570-1 (Application for Pesticide Registration)
- EPA Form 8570-34 (Certification with Respect to Citation of Data)
- EPA Form 8570-35 (Data Matrix)
- Proposed product label revised 4/24/2018
- Transmittal document
- One efficacy study (MRID 505811-01)

II. PROPOSED USE DIRECTIONS

For surfaces contaminated with viruses listed on the label:

Directions for Sanitizing Hard, Non-Porous Food Contact Surfaces: (Pathogenic Organisms):

Directions for Disinfecting surfaces:

For surfaces contaminated with the viruses listed above:

1. Prepare VigorOx® Liquid Sanitizer and Disinfectant disinfecting solution by adding 2 2/3 fluid ounce to 5 gallons of potable water. This will provide 230 ppm peroxyacetic acid and 900 ppm hydrogen peroxide. This product is effective against viruses in up to 500 ppm hard water and on surfaces with moderate soil.
2. Remove gross filth from surfaces to be disinfected by cleaning with a detergent or suitable cleaning product. Rinse with clean water.
3. Apply VigorOx® Liquid Sanitizer and Disinfectant solution by wiping, mopping, or as a coarse spray. Allow to soak for at least 5 minutes, then air dry.

III. STUDY SUMMARY

1.	MRID	50581101	Study Date:	Completion	1/4/18		
Study Objective		Disinfectant – virucidal					
Testing Lab, Lab Study ID		Microbac Laboratories, Inc., 605-122					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Avian Influenza Virus H7N9 (ATCC 15442) US CDC strain A/Anhui/1/2013 strain					
Indicator Cell Culture		MDCK cells (ATCC CCL-34)					
Test Method		Virucidal Hard Surface Efficacy Test					
Application Method		Liquid					
Test Substance Preparation	Name/ID	VigorOx [®] LS&D					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Lot 2074237 and Lot 2075739					
	Preparation	Tested concentration: LCL Dilution: 3.39 mL of test substance in 996.1 mL of diluent Diluent: 500 ppm (\pm 2.9%) AOAC hard water					
Soil load		5% serum					
Carrier type, # per lot		1 glass petri dish carrier per batch					
Test conditions		Contact time	5 min	Temp	20 \pm 1°	RH	15.9-16.4%
Neutralizer		MEM + 1% Fetal Bovine Serum (FBS) + 0.5% Polysorbate 80 + 1% HEPES + 1% NaHCO ₃ + 0.5% Na ₂ S ₂ O ₃					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)							

IV. STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log ₁₀ TCID ₅₀ /carrier)
			Batch 2074237	Batch 2075739	
5 minutes contact time, (1:294 ^a ; 5% Organic Soil Load)					
50581101	Avian Influenza Virus (H7N9)	10 ⁻² dilution	Cytotoxicity	Cytotoxicity	5.35
		10 ⁻³ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	
		Log ₁₀ TCID ₅₀ /carrier	≤2.10	≤2.10	
		Log Reduction	≥3.25	≥3..25	

^a3.39 mL test substance to 996.61 mL 500 ppm AOAC hard water

V. STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50581101	Disinfectant, virucidal	Hard, non-porous surfaces	Liquid, 1:294	5 minutes	5%	500 ppm AOAC hard water	• Avian Influenza Virus (H7N9)	Yes

VI. LABEL RECOMMENDATIONS (for label ver. 042418)

- 1.) The proposed label claims that the product, VigoOx® Liquid Sanitizer and Disinfectant, is an effective disinfectant with virucidal activity on pre-cleaned, hard, non-porous surfaces with a 5% organic soil load in 500 ppm hard water with a contact time of 5 minutes:

Avian Influenza Virus (H7N9)

This claim is acceptable as it is supported by the submitted data.

- 2.) On page 1, 3 and 7 of the proposed label, remove all claims and directions for use with the non-foaming agent, Peradigm. No data has been submitted to support the use of Peradigm in combination with the product during efficacy testing.
- 3.) On pages 1 and 3, remove claims and directions for use for sanitization of hatching eggs. This is a drug claim regulated by the FDA. Please see the following for additional information: <https://www.epa.gov/pesticide-labels/guidance-use-food-grade-shell-egg-sanitizers>
- 4.) On page 1, remove the claim "VigorOx Liquid Sanitizer and Disinfectant may be used for the non-pesticidal purpose of cleaning room surfaces by fogging"
- 5.) On page 4, under the heading "To disinfect surfaces that may be contaminated with Gram positive or Gram negative bacteria, including *S. aureus*, *S. cholerasuis* or *P. aeruginosa*:" revise "*Salmonella cholerasuis*" to "*Salmonella enterica*" to reflect the change in designation by the ATCC.
- 6.) On page 4, a contact time should be provided for "Sanitization of Shell Eggs".